

# EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff/Counterclaim Defendant,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant/Counterclaim Plaintiff.

Civil Action No. 13-1729 (SLR)

**PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION TO  
AMNEAL PHARMACEUTICALS, LLC**

Pursuant to Federal Rules of Civil Procedure 26 and 34, Plaintiff Takeda Pharmaceuticals U.S.A., Inc. requests that Defendant Amneal Pharmaceuticals, LLC produce copies of, or permit Plaintiff to inspect and copy, all documents and things responsive to these Requests at the offices of Womble Carlyle Sandridge & Rice, LLP, 8065 Leesburg Pike, Fourth Floor, Tysons Corner, VA 22182 no later than February 3, 2014 or as the parties otherwise agree or as ordered by the Court.

**INSTRUCTIONS**

A. Electronic records and computerized information must be produced in an intelligible format or together with a description of the system from which it was derived, sufficient to permit rendering the materials intelligible.

B. In producing documents and things, furnish all documents and things known or available to you regardless of whether such documents and things are possessed directly by you, or by any parent, subsidiary or affiliated corporation, or by any of your officers, directors,

employees, agents, representatives, or attorneys, or are otherwise in your possession, custody, or control.

C. If any responsive document or thing was previously possessed directly by you, or by any parent, subsidiary or affiliated corporation, or by any of your officers, directors, employees, agents, representatives, or attorneys or was otherwise in your custody or control, but is no longer, identify the document or thing, and state why it is no longer in your possession, custody or control and identify who currently has possession, custody or control of the responsive item.

D. File folders with tabs or labels identifying documents called for by these Requests must be produced intact with such documents.

E. Keep and produce a record of the source of each document or thing produced. This record shall include the name and location of the file where each document was located and the name of the person, group or department having possession, custody or control of each document or thing.

F. Documents attached to each other must not be separated.

G. Should any document or thing be withheld based on some limitation of discovery (including, without limitation, a claim of privilege) or fail to be produced due to its loss or destruction, please supply the following information:

- (1) A description of the type of document or thing (e.g., letter or memorandum);
- (2) The general subject matter of the document or identity of the thing;
- (3) The date of the document or thing;

(4) Such other information as is sufficient to identify the document or thing for a subpoena *duces tecum*, including—when indicated by the original—the author of the document, any recipients shown in the document, and, where not apparent, the relationship of the author, addressees, and recipients to each other; and

(5) The claimed ground(s) for limitation of discovery (e.g., attorney-client privilege or attorney work product) and the facts, statutes, rules, or decisions upon which the claim is founded or the circumstances of the loss or destruction of the document or thing.

H. If no documents or things are responsive to a particular Request, you are to state that no responsive documents or things exist.

I. Any redacted document should be clearly stamped with the word “REDACTED,” the portions redacted should be clearly indicated, and the reason for the redaction should be indicated.

J. If subsequent to service of an answer or objection to any Request you obtain or become aware of further documents or things pertaining to said Request, you are required to serve upon Plaintiffs an amended answer producing such documents or things, pursuant to Fed. R. Civ. P. 26(e).

K. The time period covered by these Requests—unless stated otherwise—shall be from January 1, 2009 to the present.

PLEASE TAKE NOTICE that these Requests are submitted for the purposes of discovery and are not to be taken as waiving any objections to the introduction of evidence on subjects covered by these Requests that may be made at trial or as an admission at the trial of the relevance or materiality of any of the matters covered by these requests.

## **DEFINITIONS**

As used in these Requests, the following terms have the meanings indicated below:

A. “Amneal” means defendant Amneal Pharmaceuticals, LLC and every present and former officer, director, managing agent, employee, attorney, consultant, expert, and all other persons purporting to act on behalf of Amneal Pharmaceutical, LLC, or their corporate predecessors.

B. “You” or “your” refers to Amneal, as defined above.

C. “Amneal Entity” means each individual corporate entity that is a subsidiary, affiliate, or division of Amneal Pharmaceuticals, LLC (including any corporate predecessor or successor of such subsidiary, affiliate, or division (whether partially or wholly owned)), as well as any parent company or holding company of Amneal Pharmaceuticals, LLC.

D. “Takeda” means Takeda Pharmaceuticals U.S.A., Inc.

E. “Amneal Generic Product” means any single active ingredient colchicine product for which Amneal (as defined above) and/or any Amneal Entity (as defined above) has sought FDA approval to market and sell.

F. “Paragraph IV Letter” means the written notification to Takeda dated September 9, 2013.

G. “Patents-in-suit” means U.S. Patent Nos. 7,906,519; 7,935,731; 8,093,298; 7,964,648 and 8,093,297.

H. “ANDA 204711” means the Abbreviated New Drug Application submitted by or caused to be submitted by Amneal to the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Colchicine Tablets USP, 0.6 mg.

I. “Use Code” means: the unique number assigned by the FDA describing each approved use of Colcrys®.

J. “Identify” means:

(1) In the context of a natural person, to provide the person’s (i) full name; (ii) present or last known residential address and telephone number; (iii) present or last known business address and telephone number; and (iv) present or last known place of employment and job description. If the natural person was employed at Amneal or any Amneal Entity as defined above, “identify” also means to provide (v) the title(s) of the person and the person’s dates of employment thereat. Once a person has been identified in accordance with this paragraph, only the name of that person need be listed in response to subsequent Interrogatories requiring identification of that person.

(2) In the case of a business, legal, or governmental entity or association, to provide the entity or association’s (i) full name; (ii) legal form (i.e., corporation, partnership, etc.) and state of incorporation or legal formation; (iii) address and principal place of business; (iv) officers and other persons having knowledge of the matter with respect to which the entity or association is named; and (v) the basis for its inclusion in your response.

(3) In the case of a document, to provide: (i) the identity of the person(s) originating and preparing it; (ii) the sender, if not the person who originated it; (iii) its general type (e.g., letter, memorandum, etc.), title, and identifying number; (iv) the general nature of its subject matter; (v) its date of preparation; (vi) the date and manner of any transmission, distribution or publication; (vii) the location of each copy (including title, index number and location of the file in which it is kept or from which it was removed) and the identity of the

present custodian or persons responsible for its filing or other disposition; and (viii) the identity of persons who can authenticate or identify it.

(4) In the case of a thing, to provide: (i) any model or catalogue number; (ii) any article or model name; (iii) any technical or promotional materials describing the article or its use; and (iv) the dates and locations of its production.

(5) In the case of an oral communication or meeting, to provide: (i) the date of the conversation or meeting; (ii) the location where it occurred or, in the case of an electronic communication, the location of each party; (iii) all individuals who participated or were present; (iv) the substance of what was discussed; and (v) all actions taken as a result of the communication or meeting.

K. “Including” means “including without limitation.”

L. “Communication” means any transmittal of information (in the form of facts, ideas, inquiries or otherwise) by oral, written, telephonic, electronic or radio frequency transmission, or any other means.

M. “Document” is synonymous in meaning—and equal in scope—to the usage of this term in Federal Rule of Civil Procedure 34(a), and includes any electronic or computerized compilations. A draft or non-identical copy (including copies with stamps, initials, comments, notations or other markings) is considered a separate document within the meaning of this term. This definition specifically includes e-mail or other electronic communications.

N. “Concerning” means relating to, referring to, regarding, describing, evidencing, supporting, documenting, involving or constituting.

O. The connectives “and” and “or” shall be construed either disjunctively or conjunctively as necessary to bring within the scope of a discovery request all responses that might otherwise be construed to fall outside its scope.

P. The use of the singular form of any word includes the plural and vice versa.

Q. Any pronoun shall be construed to refer to the masculine, feminine, or neutral gender, as appropriate.

### **REQUESTS FOR PRODUCTION**

#### **REQUEST FOR PRODUCTION NO. 1:**

All documents and things identified or that you are requested to identify in response to Plaintiff’s interrogatories to Amneal or concerning Amneal’s responses to those interrogatories.

#### **REQUEST FOR PRODUCTION NO. 2:**

ANDA No. 204711, and all documents and things concerning ANDA No. 204711.

#### **REQUEST FOR PRODUCTION NO. 3:**

All documents and things concerning NDA No. 22352.

#### **REQUEST FOR PRODUCTION NO. 4:**

All documents and things concerning Amneal’s Paragraph IV Letter, including without limitation any drafts of Amneal’s Paragraph IV Letter, any documents or things considered in preparing Amneal’s Paragraph IV Letter, and any meeting minutes or notes from meetings where Amneal’s Paragraph IV Letter, any drafts thereof, and/or the substance thereof was discussed.

#### **REQUEST FOR PRODUCTION NO. 6:**

All documents and things concerning the Patents-in-suit.

#### **REQUEST FOR PRODUCTION NO. 7:**

All documents and things that support, refute or relate to Amneal’s defense of non-



infringement of the claims of the Patents-in-suit.

**REQUEST FOR PRODUCTION NO. 8:**

All documents and things that support, refute or relate to any contention by Amneal that any claim or claims of the Patents-in-suit is/are invalid.

**REQUEST FOR PRODUCTION NO. 9:**

All documents and things that support, refute or relate to any contention by Amneal that the Patents-in-suit are unenforceable.

**REQUEST FOR PRODUCTION NO. 10:**

All documents and things concerning any reports, analysis, or investigation regarding the infringement and/or validity of the claims of the Patents-in-suit, and/or the enforceability of the Patents-in-suit.

**REQUEST FOR PRODUCTION NO. 11:**

All documents and things concerning any opinion(s) of counsel regarding the infringement or validity of the claims of the Patents-in-suit, and/or the enforceability of the Patents-in-suit, including without limitation any opinion(s), and/or any notes generated, prior art considered, and documents and things provided to or reviewed by anyone involved in preparing such opinion(s) of counsel.

**REQUEST FOR PRODUCTION NO. 12:**

All documents upon which you intend to rely to support any counterclaims or defenses to Plaintiffs' claims in this case.

**REQUEST FOR PRODUCTION NO. 13:**

All communications, contracts and/or agreements between Amneal and any other person or entity, including the FDA, concerning the Amneal Generic Product, ANDA No. 204711, NDA

No. 22-352, the Patents-in-suit, COLCRYS®, the above captioned litigation, single active ingredient colchicine products, and/or Amneal's plans to market products that are considered bioequivalent to COLCRYS®.

**REQUEST FOR PRODUCTION NO. 14:**

All documents and things concerning any meetings or discussions referring or relating to the Amneal Generic Product, ANDA No. 204711, NDA No. 22-352, the Patents-in-suit, COLCRYS®, the above captioned litigation, single active ingredient colchicine products, and/or Amneal's plans to market products that are considered bioequivalent to COLCRYS®, including without limitation all meeting minutes and/or notes related to any of the foregoing.

**REQUEST FOR PRODUCTION NO. 15:**

All documents and things concerning Amneal's decision to seek approval to market the Amneal Generic Product for the treatment of Familial Mediterranean Fever, including without limitation Amneal's business plans, market forecasts or financial projections, IMS data, Familial Mediterranean Fever prescription data, Familial Mediterranean Fever market analyses, and Familial Mediterranean Fever market studies.

**REQUEST FOR PRODUCTION NO. 16:**

All documents and things concerning any proposed design, development, and/or formulations, whether adopted or not, related to single active ingredient colchicine products, including without limitation the Amneal Generic Product.

**REQUEST FOR PRODUCTION NO. 17:**

All documents and things concerning any experiments, research, investigation, testing, and/or analysis related to single active ingredient colchicine products, including without limitation the Amneal Generic Product and COLCRYS®, and/or the preparation of ANDA No.

204711, including without limitation laboratory notebooks.

**REQUEST FOR PRODUCTION NO. 18:**

All documents and things used, considered, or relied upon in support of ANDA No. 204711.

**REQUEST FOR PRODUCTION NO. 19:**

All documents and things concerning the chemical and physical properties of the Amneal Generic Product.

**REQUEST FOR PRODUCTION NO. 20:**

All documents and things concerning any single active ingredient colchicine products or formulations used, considered, or relied upon in the development of the Amneal Generic Product, including without limitation COLCRYS® and any single active ingredient colchicine products or formulations referred to in ANDA No. 204711.

**REQUEST FOR PRODUCTION NO. 21:**

All documents and things concerning methods of administration of the Amneal Generic Product, including without limitation any documents concerning any research, investigation, testing, or analysis of any macrolide antibiotics or second active agents, including but not limited to clarithromycin, ketoconazole, or ritonavir, for potential use in the administration of the Amneal Generic Product.

**REQUEST FOR PRODUCTION NO. 22:**

All documents and things concerning the pharmacokinetics, absorption, bioavailability and/or bioequivalence of the Amneal Generic Product, including without limitation any publications, test results, and/or test protocols related to any of the foregoing.

**REQUEST FOR PRODUCTION NO. 23:**

All documents and things concerning any research, reports, summaries, studies, or investigations related to any single active ingredient colchicine products, including without limitation the Amneal Generic Product and COLCRYS®.

**REQUEST FOR PRODUCTION NO. 24:**

All documents and things concerning any comparisons of the Amneal Generic Product to other single active ingredient colchicine products, including without limitation comparisons to COLCRYS®.

**REQUEST FOR PRODUCTION NO. 25:**

All articles, slides, foils, speech transcripts, papers, reports, symposiums, abstracts, introductions, reviews, and/or summaries, whether published or unpublished, draft or final, concerning single active ingredient colchicine products, including without limitation those written or prepared by any past or present employee of Amneal or any Amneal Entity.

**REQUEST FOR PRODUCTION NO. 26:**

All documents and things concerning any product specifications for the Amneal Generic Product, including without limitation any proposed or draft product specifications.

**REQUEST FOR PRODUCTION NO. 27:**

All documents and things concerning any analytical or testing specifications associated with single active ingredient colchicine products, including without limitation the Amneal Generic Product and COLCRYS®, and including without limitation any proposed or draft analytical or testing specifications.

**REQUEST FOR PRODUCTION NO. 28:**

All documents and things concerning the labeling or package inserts for the Amneal

Generic Product, including changes thereto and internal communications and communications with the FDA.

**REQUEST FOR PRODUCTION NO. 29:**

All documents and things concerning advertising, marketing, or sales materials related to the Amneal Generic Product, including without limitation all documents and things concerning any possible or planned marketing materials, marketing strategies, or planned sales communications related to the Amneal Generic Product.

**REQUEST FOR PRODUCTION NO. 30:**

Documents sufficient to identify all persons who have or had at any time any involvement in the research, formulation, development, testing, manufacture, production, marketing, sale, distribution, and/or regulatory approval of the Amneal Generic Product, the products that are the subject matter of ANDA No. 204711, COLCRYS® and/or other single active ingredient colchicine products, including without limitation documents which identify the nature and scope of each such person's involvement.

**REQUEST FOR PRODUCTION NO. 31:**

All documents and things that support, refute or relate to any contention by Amneal that any COLCRYS® Use Code is improper or otherwise should be amended or withdrawn.

**REQUEST FOR PRODUCTION NO. 32:**

All documents and things that support Amneal's decision to request a label amendment for ANDA 204711 to seek approval to market the Amneal Generic Product for the treatment of Familial Mediterranean Fever.

**REQUEST FOR PRODUCTION NO. 33:**

All communications internal to Amneal and to or from the FDA regarding Amneal's

request for a label amendment for ANDA No. 204711 to seek approval to market the Amneal Generic Product for the treatment of Familial Mediterranean Fever.

**REQUEST FOR PRODUCTION NO. 34:**

All communications with Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and/or its outside counsel record in Civ. A. No. 13-1524 (SLR) concerning this litigation.

**REQUEST FOR PRODUCTION NO. 35:**

All documents and things concerning Amneal's knowledge that if ANDA No. 204711 is approved, Amneal's Generic Product will be used for the treatment and prevention of gout flares.

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/ Mary W. Bourke

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Dated: January 3, 2014

**CERTIFICATE OF SERVICE**

I hereby certify that on the 3<sup>rd</sup> day of January, 2014, I electronically served a true and correct copy of the **PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION TO AMNEAL PHARMACEUTICALS, LLC** to the below individuals:

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